

Remarks

Claims 1, 6, 9, 27, 29, 31, and 33-40 are pending. With these amendments, claims 14-20, 28, 30, and 32 are canceled. Claim 1 is amended and new claims 33-40 are added. Support for these amendments can be found throughout the specification, for example, at paragraphs [0002], [0021], [0046], [0047] and [0048], and in the claims as originally filed. No new matter is added by these amendments and entry thereof is respectfully requested.

Rejections under 35 USC §103

Claims 1, 6, 9, 14-20 and 27-32 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Young in view of Iovanna, Valter, Jorgensen, and Haddad.

Applicants respectfully traverse this rejection. The claims as amended are directed to a method of reducing or inhibiting the level of enzymatic activity or enzymatic secretion in pancreatic cells in a mammalian subject comprising administering to said subject an effective amount of an amylin or an amylin analog, wherein the amylin analog has amylin agonist activity, wherein the level of enzymatic activity or enzymatic secretion in pancreatic cells of the subject is reduced or inhibited.

Young discloses that amylin and amylin agonists can be used for analgesia in mammals. Young is completely silent regarding enzymatic activity or enzymatic secretion in pancreatic cells and does not disclose or suggest that amylin and amylin agonists can be used to reduce or inhibit the enzymatic activity or secretion in pancreatic cells. Iovanna and/or Valter are cited by the Examiner for teaching that acute pancreatitis is a painful inflammation disorder, but both references are also completely silent regarding enzymatic activity or enzymatic secretion in pancreatic cells. Jorgensen and Haddad are similarly unrelated to amylin and amylin agonists and to their biological effects on pancreatic cells.

The combination of Young and Iovanna and/or Valter, Jorgensen, and Haddad fails to disclose or suggest the biological effects of amylin and amylin agonists on pancreatic enzymes. On the other hand, Applicants describe for the first time the unexpected benefit of simultaneously

reducing pancreatic enzyme levels and relieving pain with the use of any amylin and amylin agonists (see, for example, paragraph [0048]). The skilled artisan would not have predicted that amylin and amylin analogs useful for treating pain (a therapeutic effect) would be useful for reducing pancreatic enzyme levels (a biological effect), without the benefit of Applicants' own disclosure.

As explained by the Supreme Court in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007), the appropriate analysis is to apply the *Graham* factors, which are the controlling inquiries in any obviousness analysis. Thus the scope and content of the prior art must be considered, the differences between the claimed invention and the prior art ascertained, and resolving the level of the person of ordinary skill in the art. When such analysis is performed here it is seen that no cited reference or any combination of them teaches or suggests that amylin or an amylin analog may be useful in reducing or inhibiting the level of enzymatic activity or enzymatic secretion in pancreatic cells in a mammalian subject.

Conclusion

An early and favorable consideration and allowance of Claims 1, 6, 9, 27, 29, 31, and 33-40 is respectfully requested.

Date: Novemer 19, 2010

Respectfully submitted,



Belinda M. Lew, Ph.D.
Reg. No. 53,212

Amylin Pharmaceuticals, Inc.
9360 Towne Centre Drive
San Diego, California 92121
Phone (858) 754-4230
Facsimile (858) 552-1936